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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,130	02/05/2002	Olga Bandman	PF-0319-2 DIV	2603

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FOLEY AND LARDNER
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
STEADMAN, DAVID J	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/072,130	BANDMAN ET AL.	
	Examiner	Art Unit	
	David J Steadman	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,11,12,29-45 and 58-68* is/are pending in the application.

4a) Of the above claim(s) *1,12,29,30,33,35,44 and 45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,31,32,34,36-43 and 58-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

[1] Claims 1, 11-12, 29-45, and 58-68 are pending in the application.

[2] Applicants' amendment to the claims, filed May 24, 2004, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.

[3] Claims 1, 12, 29-30, 33, 35, and 44-45 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

[4] Claims 11, 31-32, 34, 36-43, and 58-68 are being examined on the merits.

[5] Applicants' arguments filed on May 24, 2004 have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

[6] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, First Paragraph

[7] The written description rejection of claims 11, 31-32, 34, 36-43, and 58-68 are rejected under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record as set forth in item [7] of the Office action mailed February 24, 2004 and for the reasons stated below.

[8] RESPONSE TO ARGUMENTS: At the top of page 9, applicants argue that the specification provides support for the genus of antibodies of claim 11. Applicants further argue the specification sets forth conservative amino acid substitutions and describes a computer program that is employed to determine which amino acid residues can be altered without abolishing biological or immunological activity. Applicants' argument is not found persuasive.

It should be noted that, contrary to applicants' assertion, the specification fails to identify those amino acids that can be conservatively substituted resulting in a polypeptide that maintains the biological/immunological activity of SEQ ID NO:1. Regarding the merits of applicants' argument, as stated in a previous Office action, it is the examiner's position that the specification fails to describe a representative number of species to represent the entire genus of claimed antibodies, particularly in view of the wide variability of antigen structures to which the antibody binds. The specification describes only a single species of the claimed antibody – namely, an antibody that binds to the polypeptide of SEQ ID NO:1. However, in view of the open transitional phrases "comprising" or "consisting essentially of," the claims encompass antibodies that bind a widely variant genus of epitopes, including (but not limited to) any additional amino acids that may be present at the N- and/or C-terminal end(s) of SEQ ID NO:1.

At the middle of page 9, applicants argue the application describes polypeptides having phosphatase activity that share at least 95% sequence identity with SEQ ID NO:1. Applicants argue that a skilled artisan would know what amino acid changes to make such that the altered protein would maintain

phosphatase activity and could measure the activity of such variants using the disclosed assay. Applicants argue the specification describes which amino acid substitutions can be made to produce a functionally equivalent protein. Applicants' argument is not found persuasive.

It should be noted that, contrary to applicants' assertion, the specification fails to identify those amino acids that can be conservatively substituted resulting in a polypeptide that maintains the biological/immunological activity of SEQ ID NO:1. Regarding the merits of applicants' argument, the examiner acknowledges that the polypeptide is sufficiently described as evidenced by Example 14 of the "Revised Interim Written Description Guidelines Training Materials." However, the claims are not drawn to polypeptides and are instead drawn to antibodies that comprise or consist essentially of a polypeptide sequence. Thus, the issue is the description of the claimed antibody. In this regard, as stated above and reiterated herein, the claimed antibody is not sufficiently described. Applicants' attention is directed to Example 16 of "Revised Interim Written Description Guidelines Training Materials." In Example 16, the antigen used to elicit the antibody is "well characterized," however, in the instant case, the antigen used to elicit the claimed antibody is not, as the antibody can bind to amino acid sequence that is N- and C-terminal to the sequence of SEQ ID NO:1. It should also be noted that applicants' arguments suggesting that one can isolate or generate the variants of SEQ ID NO:1 for production of a cognate antibody would appear to support the examiner's argument as this would indicate that applicants did not have possession of the claimed invention at the time of filing of the instant application.

At the top of page 10 of the response, applicants argue the specification describes fragments of SEQ ID NO:1 that comprise immunogenic or enzymatic activity. Applicants argue one of skill in the art would know what is meant and how to assess and screen for the recited functionality in the claims of immunogenic and enzymatically active fragments. Applicants' argument is not found persuasive.

The instant rejection is not based upon the lack of description of fragments of the polypeptide of SEQ ID NO:1. Instead, as stated above, the rejection is based upon the recitation of open-ended transitional phrases in the claims such that the genus of claimed antibodies bind any epitope that is outside, i.e., N- or C-terminal to, an amino acid sequence comprising or consisting essentially of SEQ ID NO:1 and therefore, the genus encompasses species that bind to widely variant epitopes.

At the middle of page 10, applicants argue claim 11 has been amended to recite "consisting essentially of." Applicants' argument is not found persuasive.

While it is acknowledged that claim 11 has been amended as asserted by applicants, it is noted that claims 36, 39, 58, 65, and 68 maintain the use of the term "comprising."

Regarding amended claim 11, it is noted that, in claims reciting an amino acid sequence, the term "consisting essentially of" is usually interpreted as "comprising." Further, it should be noted that there is no evidence of record that would indicate that applicants intend for the term "consisting essentially of" to have a meaning other than "comprising." Thus, the term "consisting essentially

of" in the claims has been construed as meaning "comprising" and consequently, the claims encompass antibodies that have not been described in the specification.

[9] The scope of enablement rejection of claim(s) 11, 31-32, 34, 36-43, and 58-68 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record as set forth in item [8] of the Office action mailed February 24, 2004 and for the reasons stated below.

[10] RESPONSE TO ARGUMENTS: Applicants argue the specification is enabling for antibodies that bind to SEQ ID NO:1 and fragments and variants thereof without undue experimentation. Applicants' argument is not found persuasive.

While the claim 11 has been amended to further limit the percentage identity and to recite "consisting essentially of," this amendment does not limit the scope such that the specification enables all antibodies encompassed by the claims. As noted above, without evidence to the contrary, the term "consisting essentially of" has been interpreted as "comprising." Thus, the scope of the claims encompasses antibodies that bind to any epitope that is at the N- and/or C-terminus of SEQ ID NO:1. It should be noted that applicants have provided no evidence that would contradict the examiner's analysis of the Factors of In re Wands as presented in a previous Office and do not dispute the examiner's evidence that was provided therein demonstrating the high level of unpredictability of an antibody binding to a protein variant or a protein with additional amino acids at the N- and/or C-terminus of a given protein. See

Colman et al. (Res Immun 145:33-36) and Abaza et al. (J Protein Chem 11:433-444). As such, the examiner maintains the position that undue experimentation would be required for a skilled artisan to make the entire scope of claimed antibodies.

Conclusion

[11] Status of the claims:

- Claims 1, 11-12, 29-45, and 58-68 are pending.
- Claims 1, 12, 29-30, 33, 35, and 44-45 are withdrawn from consideration.
- Claims 11, 31-32, 34, 36-43, and 58-68 are rejected.
- No claim is in condition for allowance.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571) 272-0942. The Examiner can normally be reached Monday-Friday from 7:00 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The FAX number for submission of official papers to Group 1600 is (703) 308-4242. Draft or informal FAX communications should be directed to (571) 273-0942. Any inquiry of a general nature or relating to the

status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.
Patent Examiner
Art Unit 1652

06-24-04